Scientific and Medical Differences of Category A Pathogens

Richard Gorman, M.D.
Chair, Pediatric and Obstetrics Integrated Program Team
HHS Office of the Assistant Secretary for Preparedness and Response

Associate Director for Clinical Research
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases

PedsOB IPT

The Pediatric and Obstetric Integrated Program Team (PedsOB IPT) is established by the Public Health Emergency Medical Counter Measures Enterprise(PHEMCE) to support and assist threat-based PHEMCE IPTs with strategies for identifying, developing, acquiring, deploying, and using high priority medical countermeasures for children and pregnant women in public health emergencies.

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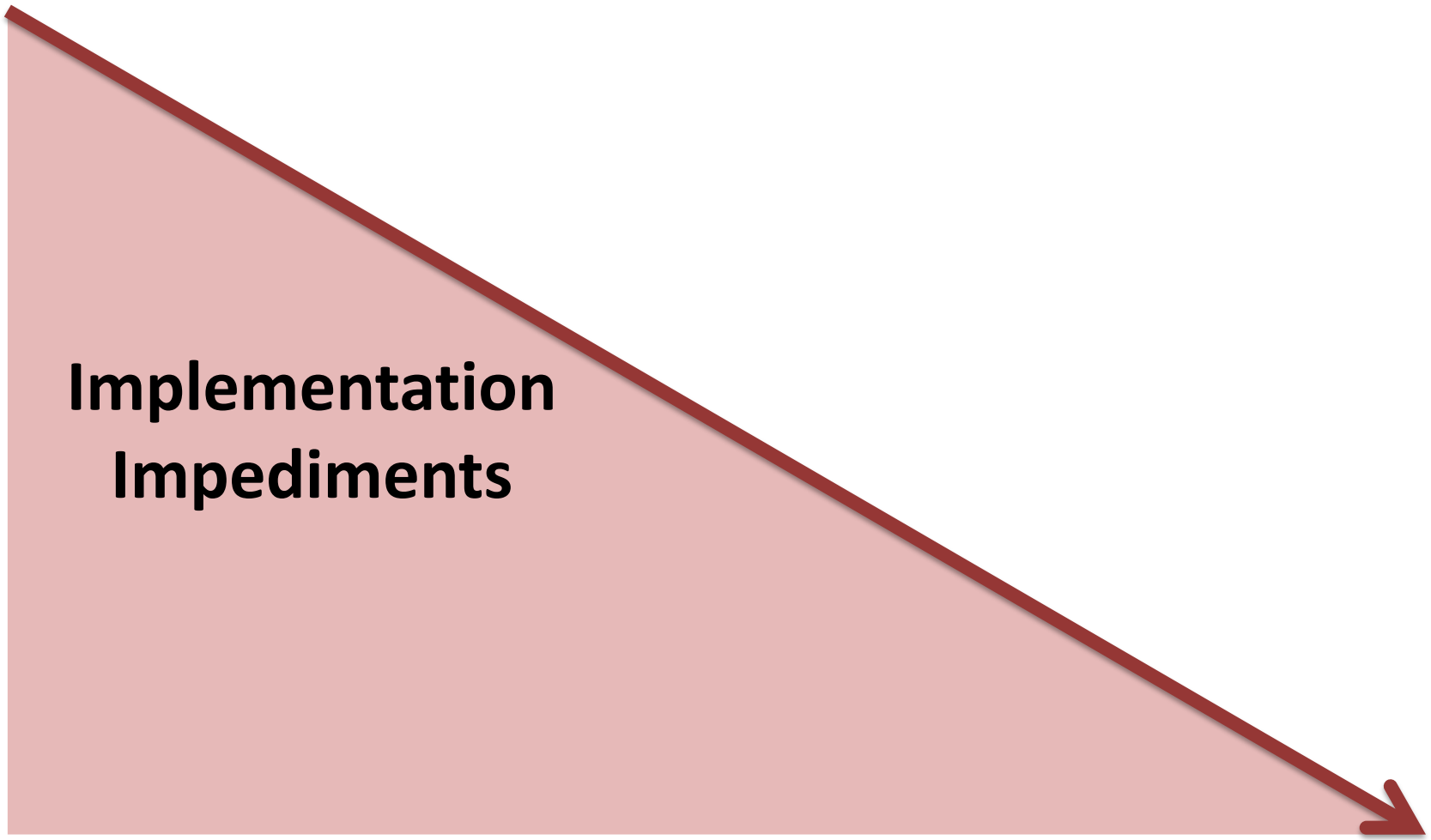

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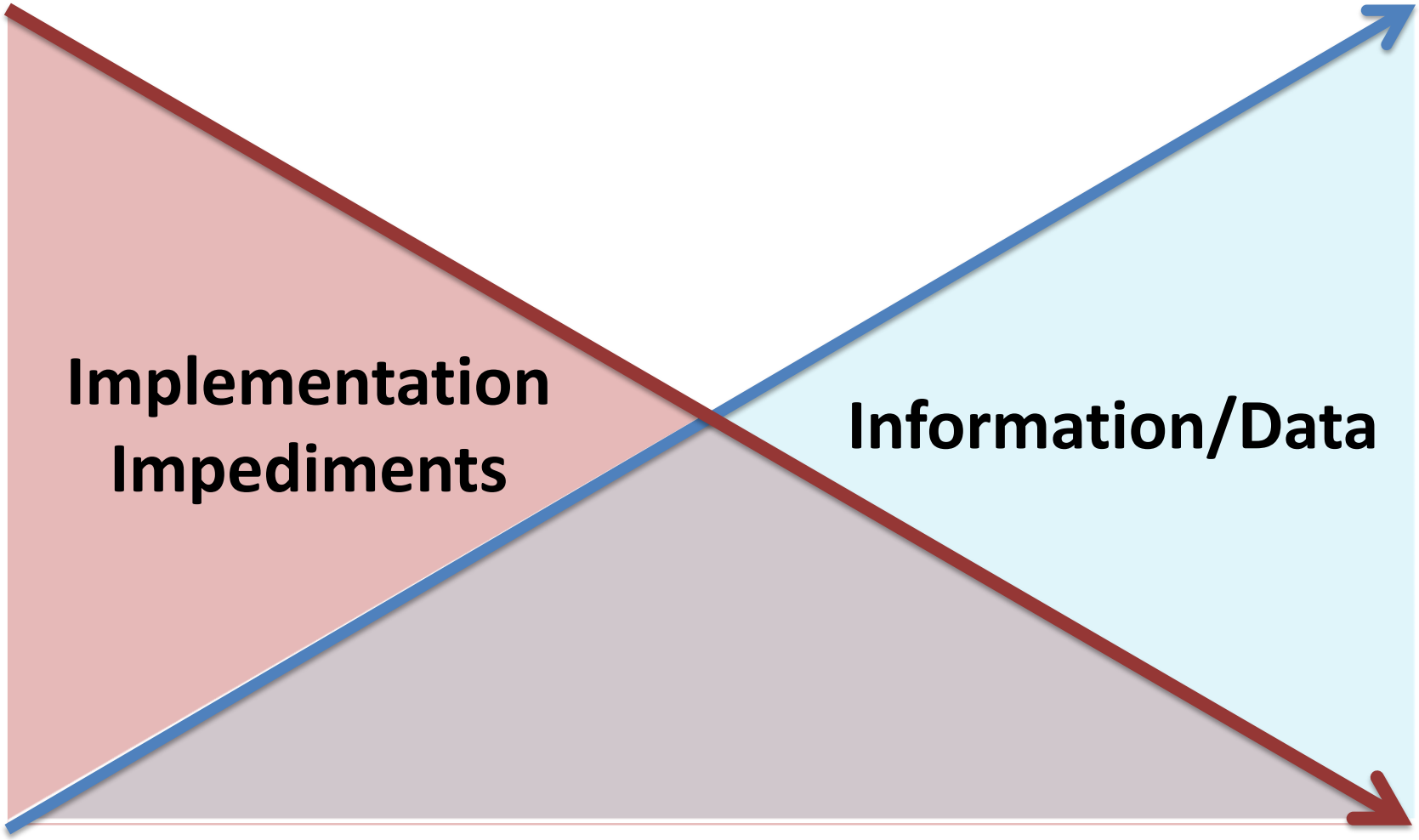


Category A Agents

Category A agents pose a **risk to national security**

- Easily disseminated or **transmitted** from person to person
- Result in **high mortality rates** and have the potential for major public health impact
- Might cause **public panic** and social disruption
- Require **special action** for public health preparedness

Biological Agents

Organisms/Biological Agents in Category A:

- Anthrax
- Botulism
- Plague
- Small Pox
- Tularemia
- Viral Hemorrhagic Fevers
  - Arenaviruses (LCM, Junin Virus, Lassa Fever)
  - Flaviviruses (Dengue)
  - Filoviruses (Ebola, Marburg)

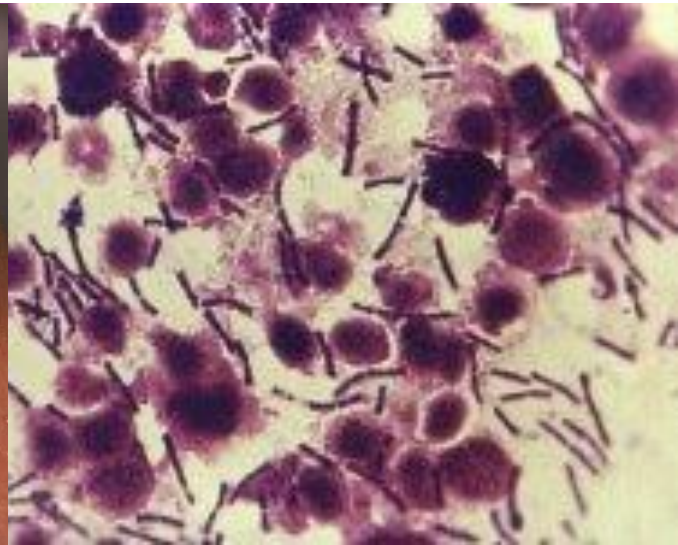
Anthrax

Organism type: Bacteria, spores

Transmission: Inhalation of spores

Untreated mortality: 75%

Cause of death: Pneumonia



Botulism

Organism type: Bacteria, spores, toxins

Transmission: Through food sources

Untreated mortality: Unknown

Cause of death: Suffocation, muscle paralysis

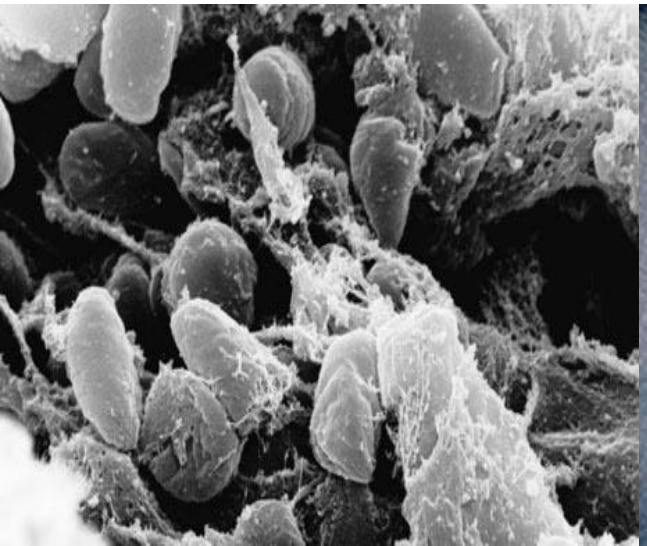
Plague ***Black Death***

Organism type: Bacteria

Transmission: Person to person, fleas

Untreated mortality: 40-90%

Cause of death: Pneumonia, shock, sepsis



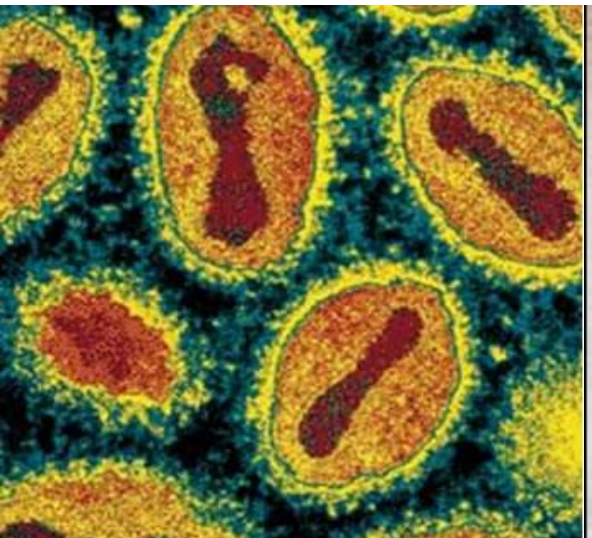
Small Pox

Organism type: Virus

Transmission: Person to person through respiratory droplets

Untreated mortality: 30%

Cause of death: Pneumonia, skin and throat infections



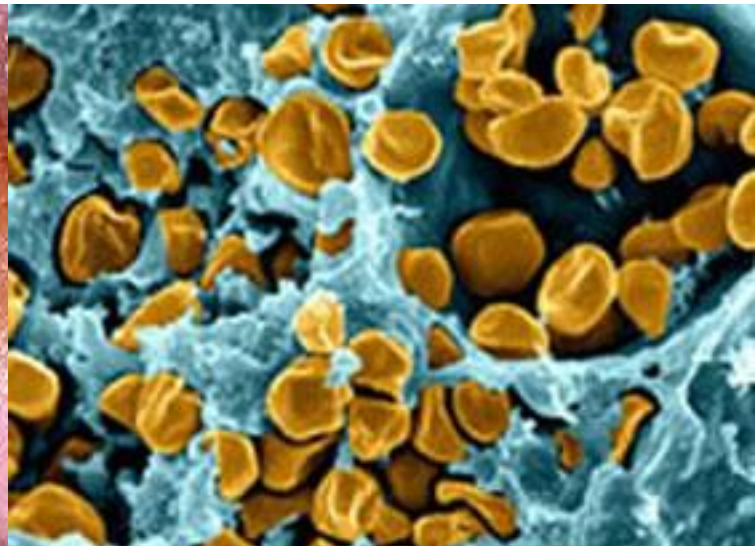
Tularemia *Rabbit Skinner's disease*

Organism type: Bacteria

Transmission: Via fleas, ticks, animal bites

Untreated mortality: <1%

Cause of death: Infection, pneumonia



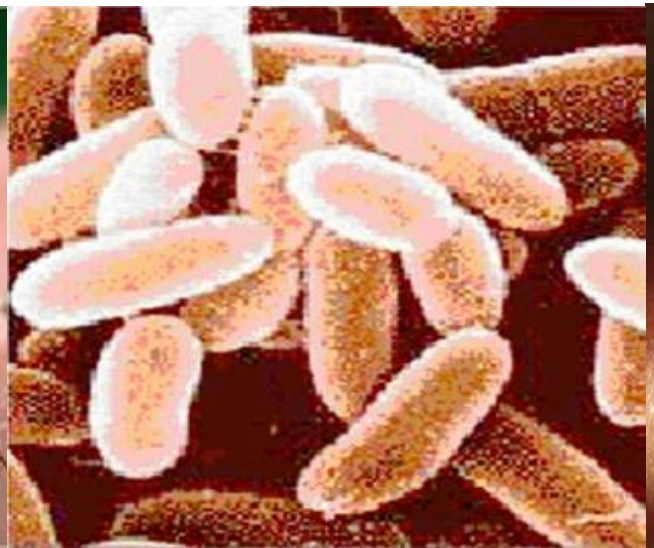
Viral Hemorraghic Fever

Organism type: Multiple organisms

Transmission: Mosquitoes, ticks, rodents

Untreated mortality: Varies

Cause of death: Bleeding



Unique Pediatric Vulnerability

Close to the ground

Anthrax, Viral hemorrhagic fever

Higher respiratory rate

Anthrax, Plague, Small pox

Smaller size

Botulism

Hand to mouth behavior

Anthrax, Botulism, Small Pox

Curiosity

Plague, Tularemia, Viral Hemorrhagic fever

Less fluid reserve

Plague

References

Anthrax:
http://jama.jamanetwork.com/article.aspx?articleid=189876

Botulism:
http://jama.jamanetwork.com/article.aspx?articleid=193600

Plague:
http://jama.jamanetwork.com/article.aspx?articleid=192665

Small Pox:
http://jama.jamanetwork.com/article.aspx?articleid=190320

Tularemia:
http://jama.jamanetwork.com/article.aspx?articleid=193894

Viral Hemorrhagic Fever:
http://jama.jamanetwork.com/article.aspx?articleid=194908a

Studies that could inform

- Palatability
- Route of vaccine administration for children
- Liquid formulation
- Absorption, distribution, metabolism, excretion
  Dose finding for children and pregnant women
- The execution of any of these studies raises ethical concerns

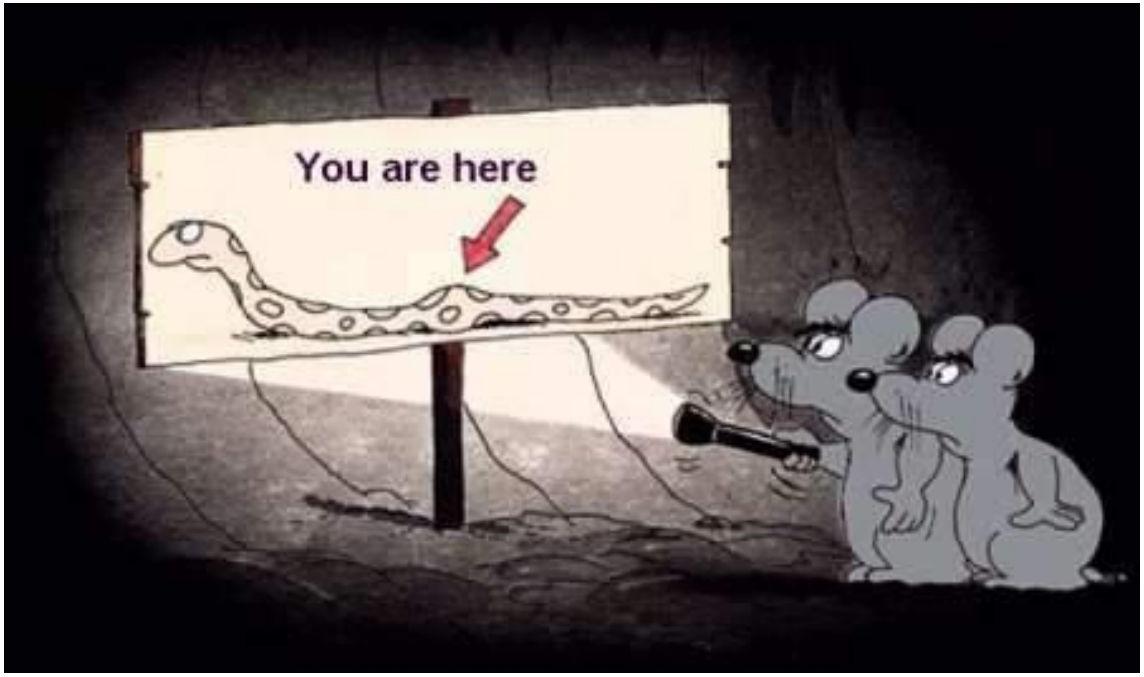
One such study…

Palatability

- **Ciprofloxacin** is a treatment for anthrax and pneumonic plague
- **Cost** and production constraints prevent the **Strategic National Stockpile(SNS)** from being able to acquire adequate amounts of “liquid medicine” to treat all who might need it
- Children and adults with **swallowing difficulties** will get crushed pills

Palatability

- Ciprofloxacin is **not the first line treatment** for any childhood infection
- Palatability would be tested on **healthy children**
- Using the paradigm presently applied to the study of anthrax vaccine
- The study would present **more than minimal risk** with **no prospect of direct benefit**
- Study would need a **45 CFR 46.407/ 21 CFR 50.54 review**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